



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,449	03/26/2004	Paul J. DeGroot	P-9891.05	8960

27581 7590 06/05/2007
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER

PATEL, NATASHA

ART UNIT	PAPER NUMBER
----------	--------------

3766

MAIL DATE	DELIVERY MODE
-----------	---------------

06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,449	Applicant(s) DEGROOT ET AL.	
	Examiner Natasha N. Patel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on March 12, 2007 has been received and considered. By this amendment, Claims 1-3, 10, 13, 18, and 20-21 have been amended and Claims 31-33 have been added.

Double Patenting

In view of the filing of a terminal disclaimer, the Examiner is withdrawing the obviousness-type/statutory double patenting rejection of claims 1-30, which was made in the last Office Action.

Claim Objections

1. In view of the Applicant's amendment to Claims 2, 3, 20, and 21, the Examiner is withdrawing the objection, which was made in the last Office Action.
2. The objection to Claims 8, 9, and 15 made in the previous Office Action stands. No amendments were made to these claims despite the following objections:
3. Claims 8 and 9 are objected to because of the following informalities: It is unclear as to what the second parameter refers to in Claim 8 until one reads Claim 9. It is suggested that these two claims be switched to prevent any misunderstandings. Appropriate correction is required.
4. Claim 15 is objected to because of the following informalities: VT is undefined in the claims. Acronyms should be spelled out at least for the first instance they are introduced. Appropriate correction is required.

Response to Arguments

5. Applicant's arguments, see pages 8-10, filed March 12, 2007, with respect to the rejection(s) of claim(s) 1-33 under 35 USC §102(b) as being anticipated by Drane and Causey have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, arguments against the rejection of Claims 1, 2, and 18 under 35 USC §102(b) as being anticipated by Olson have not been persuasive.
6. According to Figure 2, the start time of the anti-tachycardia pacing (see pacing pulse 76) is approximately simultaneous with the charging of the output capacitors (see line 70). It is evident from this, that the timing is pretty close to each other.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 18, 20, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Olson (US Patent 5,458,619).
9. Regarding Claims 1 and 18, Olson discloses a system for use in controlling electrical therapy delivered to a heart (see col. 2, lines 54-60), comprising: a first circuit that is charged (see high voltage charging circuitry 52) to deliver high-voltage electrical stimulation to the heart; a second circuit (see pacer circuitry 10) to deliver anti-tachy pacing (ATP) therapy to the heart; a control circuit (see control circuitry 4) coupled to

Art Unit: 3766

the first and second circuits (see Figure 1) to adjust a time of charging of the first circuit relative to a time of delivering ATP therapy based on predetermined criteria (see col. 1, line 63-col. 2, line 5).

10. Regarding Claims 2 and 20, Olson discloses the control circuit includes means for operating in an ATP-DCC mode to initiate charging of the first circuit during delivery of the ATP therapy (see col. 1, lines 61-62).

11. Regarding Claim 31, Olson discloses aborting delivery of high-voltage stimulation in response to determining the sensed abnormal cardiac rhythm has terminated (see col. 2, lines 6-24).

12. Regarding Claim 32, Olson discloses the second circuit delivers one or more sequences of ATP therapy during charging of the first circuit (see col. 6, lines 7-10).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 3, 4, 12, 13, 19, 21, 22, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,458,619) in view of Causey et al. (US Patent 5,318,591).

Art Unit: 3766

15. Regarding Claims 3 and 21, Olson does not disclose the ATP-BCC mode.

Causey discloses a similar system in which the control circuit includes means for operating in an ATP-BCC mode to initiate charging of the first circuit after the delivery of the ATP therapy (see col. 3, lines 61-64). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Causey's ATP-BCC mode because he teaches that doing so helps verify the successful termination of tachyarrhythmia before other stronger therapies are needlessly applied (see col. 3, lines 60-68).

16. Regarding Claims 4 and 22, Causey discloses the control circuit includes means for transitioning between the ATP-BCC mode and the ATP-DCC mode based on predetermined criteria related to the effectiveness of the previously-delivered ATP therapy (see Figure 3). The examiner considers that the control circuit is in ATP-DCC mode between t6 and t7 (ATP and charging occurs), and transitions to BCC mode from t7 to t8 (charging occurs after ATP has been delivered). The examiner further considers that the verification step, performed by the sensing circuit and the control circuit (see col. 10, lines 3-7), is the means for transitioning. Furthermore, the effectiveness of the ATP therapy is monitored by determining how successful or unsuccessful the therapy is at terminating the abnormal rhythm (see col. 12, lines 3-16). The amount of time spent delivering ATP therapy is based on the predetermined set of criteria, or programmed number of times that the therapy is allowed to fail before the next tier of therapy is applied.

17. Regarding Claims 12 and 19, Olson discloses the use of a random access memory (see col. 2, lines 55-64) coupled to the control circuit (microprocessor 2) for storing predetermined criteria. Olson does not disclose that the criteria are programmably selected. Causey discloses a storage device (see memory 44) coupled to the control circuit (see Figure 1) to store the predetermined criteria (see col. 13, lines 25-35), and wherein the predetermined criteria are programmably selected (see col. 14, lines 5-8) to be specific to a given patient (see col. 15, lines 19-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to have the criteria programmably selected because Causey teaches that it saves time and allows for immediate therapy delivery (see col. 14, lines 15-20).

18. Regarding Claim 13, Olson discloses sensing the heart rhythm during charging (see col. 2, lines 11-15). Causey discloses at least one electrode coupled to the control circuit capable of detecting rhythms of the heart (see col. 7, lines 30-42), and wherein the predetermined criteria is based on a length of one or more of the sensed cardiac rhythms. Since the control circuit 22 measures heart rate (see col. 7, lines 35-42) and information concerning the length of a cardiac rhythm is included in the heart rate, then control unit 22 takes the length of the cardiac rhythm into consideration when programming the predetermined criteria (see col. 7, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the heart rhythm to determine predetermined criteria because Causey teaches that it allows the microprocessor to create a more appropriate therapy (see col. 3, lines 54-64).

Art Unit: 3766

19. Regarding Claim 30, Causey discloses further including discontinuing step a.) after unsuccessfully delivering ATP therapy a predetermined number of times (see col. 12, lines 6-9 and Figure 3). For example, after three unsuccessful deliveries of ATP therapy, ATP therapy is discontinued (at t7).

20. Claims 5-11, 23-26, 29, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,458,619) in view of Causey, III et al. (US Patent 5,318,591) as applied to Claim 1 above, and further in view of Sun et al. (US Patent 6,400,986).

21. Regarding Claims 5 and 24, Causey does not disclose a transition from ATP-BCC mode to ATP-DCC mode based on ATP therapy failure. Sun discloses a similar control system in which the transitioning modes based on the number of failed ATP therapy attempts to provide a means to effectively alter the therapy so the arrhythmia is rapidly and effectively treated so as to not require a defibrillation shock (see col. 2, lines 13-17 and col. 7, lines 33-35). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to charge Causey's capacitors during ATP to avoid unnecessary defibrillation therapy (see col. 2, lines 13-17).

22. Regarding Claim 6, Causey discloses the first parameter is measured as a number of failed ATP attempts out of a total number of ATP therapy attempts delivered (see col. 14, lines 2-14). The examiner considers that even if the ATT pacing is not repeated and the ICD steps up to the next tier, the number of failed attempts (1 failure) out of a total number of attempts (1 attempt) is still programmed into the control unit.

23. Regarding Claims 7 and 25, Causey does not disclose a transition from ATP-DCC mode to ATP-BCC mode in the case that ATP therapy is successful. Sun discloses transitioning modes based on the number of successful ATP therapy attempts in the ATP-DCC mode to provide a means to effectively alter the therapy so the arrhythmia is rapidly and effectively treated so as to not require a defibrillation shock (see col. 2, lines 13-17 and col. 7, lines 35-38).

24. Regarding Claim 8, Causey discloses a programmable (see col. 8, lines 26-27) storage device (see memory 44) coupled to the control circuit (see Figure 1) to store the predetermined criteria (see col. 14, lines 5-8).

25. Regarding Claim 9, Causey discloses the second parameter is measured as a number of successful ATP attempts out of a total number of ATP therapy attempts delivered (see col. 13, line 66-col. 14, line 2). The examiner considers that when the ATT pacing is successful, the ICD is inherently checking for a ratio of successful attempts (1 success) to a total number of attempts (1 attempt), which is programmed into the control unit.

26. Regarding Claim 10, Causey discloses at least one electrode (electrode 32) coupled to the control circuit (see Figure 1) to sense cardiac rhythms (see col. 7, lines 31-34), and a processing circuit (logic circuits) coupled to the control circuit to analyze types of the cardiac rhythms (see col. 8, lines 12-15), and wherein the predetermined criteria takes into account the types of the cardiac rhythms (see col. 8, lines 15-26) occurring in the heart. The examiner considers that the different types of cardiac rhythms include: normal, tachycardia, and fibrillation.

Art Unit: 3766

27. Regarding Claim 11, Causey discloses that the control circuit includes means for utilizing different values for the first and second parameters, each of the values being respectively associated with a type of cardiac rhythm occurring during delivery of the ATP therapy (see col. 12, lines 3-16 and col. 13, lines 25-35). The examiner considers that in the specific example give in column 12, the first parameter is set to three for first tier therapy, one for second tier therapy, and one for third tier therapy, where each tier represents a type of cardiac rhythm. Thus, it is evident that different values are assigned for each tier.

28. Regarding Claim 23, see rejections of similarly worded Claims 5 and 7 above.

29. Regarding Claims 26, 29, and 33, Causey discloses analyzing the rate and regularity of cardiac rhythms in the heart (see col. 7, line 40-42). Causey does not disclose analyzing the morphology, however. Sun discloses analyzing morphology of cardiac rhythms detected in the heart and wherein the predetermined set of criteria in step c.) is based on the morphology of cardiac rhythms detected in the heart (see col. 5, lines 49-56). Sun further discloses changing modes based on change in morphology of the rhythm (see col. 3, lines 49-51). Sun also discloses the transitions are made in response to a length of an episode corresponding to previously delivered ATP therapy (see col. 3, lines 14-36). It would be obvious to one of ordinary skill in the art at the time of the invention to analyze the morphology and timing of cardiac rhythms because Sun teaches that it helps to differentiate between VT's and fibrillations (see col. 5, lines 56-60) thereby allowing Causey's control system to provide an appropriate therapy.

Art Unit: 3766

30. Claims 14-17 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,458,619) and Causey, III et al. (US Patent 5,318,591) in view of Sun et al. (US Patent 6,400,986) as applied to Claims 5-10 above, and further in view of Haluska et al. (US Patent 4,830,006).

31. Regarding Claims 14-15 and 27-28, Causey discloses means for adjusting the time of charging of the first circuit relative to the time of delivering ATP therapy (see col. 11, lines 34-56). Causey does not disclose that this adjustment is based on the frequency of occurrence of one or more of the cardiac rhythms. Haluska discloses adjusting therapy based on a frequency of occurrence of the rhythm to provide rapid and effective treatment (see col. 7, lines 38-44 and col. 13, line 29-col. 14, line 36). The examiner considers that the detection of VT storms, wherein a predetermined number of VT rhythms are detected within a predetermined period of time, is equivalent to the frequency of occurrence of a VT, a specific cardiac rhythm. It would have been obvious to one of ordinary skill in the art at the time of the invention to adjust therapy based on how frequently a specific type of cardiac rhythm occurs in order to manage the arrhythmia appropriately and allocating only what energy is necessary for each type of therapy.

32. Regarding Claims 16 and 17, Causey discloses that the predetermined criteria includes criteria associated with a change in a type of cardiac rhythm occurring prior to the delivery of the ATP therapy (see col. 9, lines 62-65). The examiner considers that the ICD is programmed to recognize the change from a normal cardiac rhythm to a tachycardia rhythm and is therefore a predetermined criterion that is necessarily

Art Unit: 3766

incorporated into the ICD. Causey does not explicitly disclose that the criteria are associated with a change in a type of cardiac rhythm during the delivery of ATP therapy. Haluska discloses transitioning therapy modes based on a change in rhythm during ATP therapy (see col. 7, lines 38-44; col. 9, lines 17-22; and col. 13, lines 58-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to allow Causey's control system to transition between modes during ATP therapy because Haluska teaches the benefit of having additional or backup capabilities for terminating tachycardias in the event of acceleration and reducing the risks involved with more serious cardiac arrhythmias.

Conclusion

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

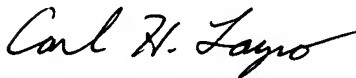
34. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

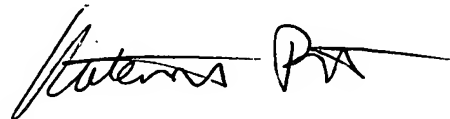
36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carl H. Layno
Acting Supervisory Patent Examiner
5/25/07

CARL LAYNO
PRIMARY EXAMINER



Natasha N Patel
Patent Examiner
Art Unit 3766